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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/709,131	11/10/2000	Ronald B. Gartenhaus	9598-30U1	4043
8933 7590 04/04/2007 DUANE MORRIS, LLP IP DEPARTMENT 30 SOUTH 17TH STREET PHILADELPHIA, PA 19103-4196			EXAMINER UNGAR, SUSAN NMN	
			ART UNIT	PAPER NUMBER
			1642	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/04/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/709,131

Applicant(s)

GARTENHAUS, RONALD B.

Examiner

Susan Ungar

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 09 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 14-17, 32-37 and 40-47 is/are pending in the application.
- 4a) Of the above claim(s) 14-27 and 42-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 32-37, 40-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

1. The Amendment filed February 9, 2007 in response to the Office Action of August 7, 2006 is acknowledged and has been entered. Previously pending claims 35, 40-41 has been amended. Claims 32-37 and 40-41 are currently being examined.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The following rejections are being maintained:

Claim Rejections - 35 USC 101

4. Claims 32-37 and 40-41 remain rejected under 35 USC 101 for the reasons previously set forth in the paper mailed August 7, 2006, Section 5, pages 2-12.

Applicant argues that the involvement of MCT-1 protein in cell cycle regulation and in cancer has been conclusively demonstrated in the published literature and points to two published papers and an abstract of a third published paper wherein the two published papers, one published in 2005 (seven years after the priority date of the instant application which is May 11, 1998) and one in 2003 (five years post priority date), demonstrate MCT-1 is overexpressed in cancerous cells and the abstract, also published in 2005 demonstrates the accepted role of MCT-2 in cell cycle regulation. The argument has been considered but has not been found persuasive because as clearly set forth in the utility rejection, additional work was required in order to establish that the claimed invention had utility. Clearly additional work has now been done. However, in order to satisfy the requirements of 35 USC 101, an invention must be found to have utility at the time of filing in order to satisfy the requirements of 35 USC 101, see MPEP 2107-II. Clearly, for the reasons previously set forth the claimed invention did not satisfy the requirements of 35 USC 101 and was found to lack utility.

The arguments have been considered but have not been found persuasive and the rejection is maintained.

Claim Rejections - 35 USC 112

5. Claims 32-37 and 40-41 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in the paper mailed August 7, 2006, Section 7, page 12.

Applicant argues that given the information submitted drawn to the rejection under 35 USC 101, this rejection should be withdrawn for the same reasons presented in connection with the rejection under 35 USC 101. The argument has been considered but has not been found persuasive for the reasons set forth above.

The arguments have been considered but have not been found persuasive and the rejection is maintained.

6. Claim 33 remains rejected under 35 USC 112, first paragraph for the reasons previously set forth in the paper mailed August 7, 2006, Section 10, page 15.

Applicant argues that the disclosures at page 17, lines 19-20 at which the homologous region of amino acid residues 1-114 of SEQ ID NOS 2 and 8 is disclosed and claim 14 and page 17 lines 16-19 of the specification which recite at least ten or twenty consecutive residues of such sequences, together with those previously cited, constitute an adequate written description of the subject matter claimed.

The argument has been considered but has not been found persuasive because a review of page 17, lines 16-20 reveals support for "The invention further relates to an isolated polypeptide which is homologous with at least a portion of MCT-1. The isolated polypeptide of the invention is preferably homologous with at least about ten, fifteen, twenty, or more amino acid residues of SEQ ID NO: 8,

which is listed in Figure 5B. It is understood that SEQ ID NOs: 2 and 8 are identical at amino acid residues 1 to 114. Therefore, these two sequences may be used interchangeably, except that use of SEQ ID NO: 8 is preferred when the identity of one or more of amino acid residues 115 to 181 is critical.” And a review of claim 14 as originally filed reveals support for “An isolated polypeptide having an amino acid sequence which comprises at least about ten consecutive amino acid residues of SEQ ID NO: 8.” The cited support has been considered but has not been found persuasive because none of the cited support discloses or suggests an antibody that binds with specificity to a portion of MCT-1 wherein the portion includes at least ten consecutive amino acid homologous residues of 1-114 of SEQ ID NOS 2 or SEQ ID NO:8. In particular, the citation at page 17 simply states that the invention includes isolated polypeptide that is preferably homologous with at least ten, fifteen twenty or more amino acid residues of SEQ ID NO:8 and that SEQ ID NOS 2 and 8 are identical at amino acid residues 1 to 114. No antibody is contemplated here, no antibody binding is contemplated here. Further, although claim 14 is drawn to a polypeptide that comprises at least about ten consecutive amino acid residues of SEQ ID NO:8, again, no antibody is contemplated here, no antibody binding is contemplated here and the limitation of binding the claimed residues, wherein the residues are within amino acids 1-114 of SEQ ID Nos:2 and 8 is neither mentioned nor contemplated here. The argument has been considered but has not been found persuasive and the rejection is maintained.

The arguments have been considered but have not been found persuasive and the rejection is maintained.

7. Claim 34 remains rejected under 35 USC 112, first paragraph for the reasons previously set forth in the paper mailed August 7, 2006, Section 11, pages 15-16.

Applicant argues that the disclosures at page 17, lines 19-20 at which the homologous region of amino acid residues 1-114 of SEQ ID NOS 2 and 8 is disclosed and claim 14 and page 17 lines 16-19 of the specification which recite at least ten or twenty consecutive residues of such sequences, together with those previously cited, constitute an adequate written description of the subject matter claimed.

The argument has been considered but has not been found persuasive because a review of page 17, lines 16-20 reveals support for "The invention further relates to an isolated polypeptide which is homologous with at least a portion of MCT-1. The isolated polypeptide of the invention is preferably homologous with at least about ten, fifteen, twenty, or more amino acid residues of SEQ ID NO: 8, which is listed in Figure 5B. It is understood that SEQ ID NOs: 2 and 8 are identical at amino acid residues 1 to 114. Therefore, these two sequences may be used interchangeably, except that use of SEQ ID NO: 8 is preferred when the identity of one or more of amino acid residues 115 to 181 is critical." And a review of claim 14 as originally filed reveals support for "An isolated polypeptide having an amino acid sequence which comprises at least about ten consecutive amino acid residues of SEQ ID NO: 8." The cited support has been considered but has not been found persuasive because none of the cited support discloses or suggests an antibody that binds a portion of MCT-1 wherein that portion is at least about ten consecutive amino acid residues of SEQ ID NO:8. In particular, the citation at page 17 simply states that the invention includes isolated polypeptide that is preferably homologous with at least ten, fifteen twenty or more amino acid residues of SEQ ID NO:8 and that

SEQ ID NOS 2 and 8 are identical at amino acid residues 1 to 114. No antibody is contemplated here, no antibody binding is contemplated here. Further, although claim 14 is drawn to a polypeptide that comprises at least about ten consecutive amino acid residues of SEQ ID NO:8, again, no antibody is contemplated here, no antibody binding is contemplated here.

The argument has been considered but has not been found persuasive and the rejection is maintained.

8. Claim 35 remains rejected under 35 USC 112, first paragraph for the reasons previously set forth in the paper mailed August 7, 2006, Section 12, pages 16-17.

Applicant argues that the disclosures at page 17, lines 19-20 at which the homologous region of amino acid residues 1-114 of SEQ ID NOS 2 and 8 is disclosed and claim 14 and page 17 lines 16-19 of the specification which recite at least ten or twenty consecutive residues of such sequences, together with those previously cited, constitute an adequate written description of the subject matter claimed.

The argument has been considered but has not been found persuasive because a review of page 17, lines 16-20 reveals support for "The invention further relates to an isolated polypeptide which is homologous with at least a portion of MCT-1. The isolated polypeptide of the invention is preferably homologous with at least about ten, fifteen, twenty, or more amino acid residues of SEQ ID NO: 8, which is listed in Figure 5B. It is understood that SEQ ID NOs: 2 and 8 are identical at amino acid residues 1 to 114. Therefore, these two sequences may be used interchangeably, except that use of SEQ ID NO: 8 is preferred when the identity of one or more of amino acid residues 115 to 181 is critical." And a review of claim 14 as originally filed reveals support for "An isolated polypeptide

having an amino acid sequence which comprises at least about ten consecutive amino acid residues of SEQ ID NO: 8.” The cited support has been considered but has not been found persuasive because none of the cited support discloses or suggests an antibody that binds a portion of MCT-1 wherein that portion includes amino acid residues 1-20 SEQ ID NO:8. In particular, the citation at page 17 simply states that the invention includes isolated polypeptide that is preferably homologous with at least ten, fifteen twenty or more amino acid residues of SEQ ID NO:8 and that SEQ ID NOS 2 and 8 are identical at amino acid residues 1 to 114. No antibody is contemplated here, no antibody binding is contemplated here. Further, although claim 14 is drawn to a polypeptide that comprises at least about ten consecutive amino acid residues of SEQ ID NO:8, again, no antibody is contemplated here, no antibody binding is contemplated here. Further, there is no contemplation in the cited support wherein the antibody binds to a portion which includes amino acid residues 1-20.

The argument has been considered but has not been found persuasive and the rejection is maintained.

12. All other objections and rejections recited in the previous paper are withdrawn.

13. No claims allowed.

14. This action is a **final rejection** and is intended to close the prosecution of this application. Applicant's reply under 37 CFR 1.113 to this action is limited either to an appeal to the Board of Patent Appeals and Interferences or to an amendment complying with the requirements set forth below.

If applicant should desire to appeal any rejection made by the examiner, a Notice of Appeal must be filed within the period for reply identifying the rejected

claim or claims appealed. The Notice of Appeal must be accompanied by the required appeal fee.

If applicant should desire to file an amendment, entry of a proposed amendment after final rejection cannot be made as a matter of right unless it merely cancels claims or complies with a formal requirement made earlier. Amendments touching the merits of the application which otherwise might not be proper may be admitted upon a showing a good and sufficient reasons why they are necessary and why they were not presented earlier.

A reply under 37 CFR 1.113 to a final rejection must include the appeal from, or cancellation of, each rejected claim. The filing of an amendment after final rejection, whether or not it is entered, does not stop the running of the statutory period for reply to the final rejection unless the examiner holds the claims to be in condition for allowance. Accordingly, if a Notice of Appeal has not been filed properly within the period for reply, or any extension of this period obtained under either 37 CFR 1.136(a) or (b), the application will become abandoned. This action is a **final rejection** and is intended to close the prosecution of this application. Applicant's reply under 37 CFR 1.113 to this action is limited either to an appeal to the Board of Patent Appeals and Interferences or to an amendment complying with the requirements set forth below.

If applicant should desire to appeal any rejection made by the examiner, a Notice of Appeal must be filed within the period for reply identifying the rejected claim or claims appealed. The Notice of Appeal must be accompanied by the required appeal fee.

If applicant should desire to file an amendment, entry of a proposed amendment after final rejection cannot be made as a matter of right unless it

merely cancels claims or complies with a formal requirement made earlier.

Amendments touching the merits of the application which otherwise might not be proper may be admitted upon a showing a good and sufficient reasons why they are necessary and why they were not presented earlier.

A reply under 37 CFR 1.113 to a final rejection must include the appeal from, or cancellation of, each rejected claim. The filing of an amendment after final rejection, whether or not it is entered, does not stop the running of the statutory period for reply to the final rejection unless the examiner holds the claims to be in condition for allowance. Accordingly, if a Notice of Appeal has not been filed properly within the period for reply, or any extension of this period obtained under either 37 CFR 1.136(a) or (b), the application will become abandoned.

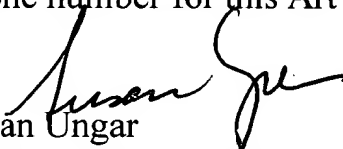
15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

Art Unit: 1642

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley, can be reached at 571-272-0898. The fax phone number for this Art Unit is (571) 273-8300.



Susan Ungar

Primary Patent Examiner

March 27, 2007